

Considered - RMK

**PATENT**

Attorney Docket No.: A-72186  
Attorney File No.: 471702-00005

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of:

QI et al.

Serial No. 10/804,762

Filing Date: March 19, 2004

For: *Specific Inhibition of Allorejection*

Examiner: KELLY, Robert M.

Art Unit: 1633

Confirmation No. 8100

CERTIFICATE OF ELECTRONIC TRANSMISSION

I hereby certify that this correspondence, including listed enclosures, is being electronically transmitted in Portable Document Form (PDF) through EFS-Web via Hyper Text Transfer Protocol to the United States Patent and Trademark Office's Patent Electronic Business Center on:

Dated: May 25, 2007

Signed:

*Ann-Ellice Parker*

**DECLARATION  
Pursuant to § 1.132**

The undersigned, Dr. Uwe Staerz, hereby declares as follows:

1. I received my Ph.D. in Immunology in 1986. A copy of my curriculum vitae is attached. I am employed by Isogenis, Inc., the assignee of the above-referenced application and currently serve Chief Scientific Officer of the company.
2. I have read and am familiar with the disclosure in the above-referenced application and have reviewed as well the Examiner's comments in his most recent office action mailed November 30, 2006.
3. I understand that the Examiner has a number of concerns regarding the extent to which the claimed invention works. Specifically, the Examiner is concerned about whether immune responses other than adaptive CTL immunity are affected; about the timing of the immune inhibitory effects; and again about the level of CD8 alpha chain expression obtainable in allograft tissues. I also understand that the Examiner is concerned about the novelty of using a vector encoding CD8 alpha alone instead of a vector encoding CD8 alpha and beta chains *in vivo*. I will address the latter concern first by beginning with a brief overview of the state of the art in CD8 veto technology as of our priority date (March 19, 2003).
4. By 2003, veto was understood to be a specific immune inhibitory function exerted by hematopoietic cells, such as cytotoxic T lymphocytes and certain bone marrow-derived cells. Indeed, the scientific community in 2003 considered that only hematopoietic cells could exert a